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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/511,112	10/21/2004	Noboru Tsuchimori	2007_0561	6413

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EXAMINER	
SPIVACK, PHYLLIS G	

ART UNIT	PAPER NUMBER
1614	

MAIL DATE	DELIVERY MODE
10/09/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/511,112	TSUCHIMORI ET AL.	
	Examiner	Art Unit	
	Phyllis G. Spivack	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 June 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,4,6,8 and 12* is/are pending in the application.

4a) Of the above claim(s) *4,6 and 8* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3 and 12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☒ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Applicants' Amendment filed June 30, 2009 is acknowledged. Claims 2, 5, 7 and 9-11 are canceled.

In the Response filed March 11, 2008 to a requirement for an Election of Species, Applicants elected the specie 1-acetyl -N-(3-{4-[4-(aminocarbonyl)benzyl)-1-piperidinyl}propyl)-N-(3-chloro-4-methylphenyl)-4-piperidinecarboxamide, which is also known as TAK 220. Applicants noted this compound is recited only in claim 3. The elected compound is not recited in instant claim 4. This claim was inadvertently included in the examination of the last two Office Actions. Claim 4 is withdrawn from consideration as drawn to non-elected inventions. On November 27, 2007, in response to an Election of Species Requirement, Applicants elected the disease graft-versus-host disease.

The subject matter under consideration remains those methods for the treatment of graft-versus-host disease and/or rejection reactions during heart, kidney, liver or bone marrow transplantation comprising administering TAK 220. Claims 6 and 8 remain withdrawn from consideration by the Examiner, as directed to non-elected inventions, 37 CFR 1.142(b). Accordingly, claims 1, 3 and 12 remain under consideration.

Rejections set forth in the last Office Action that are not herein reiterated are withdrawn. The following rejections constitute the only rejections presently applied to the instant claims.

Claim 1, 3, 4 and 12 were rejected under 35 U.S.C. 112, first paragraph, in the last Office Action because the specification, while being enabling for showing the preparation of various dosage forms and for the preparation of compounds having a

CCR antagonist effect, does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

Applicants argue the Experimental Example on pages 321-322 of the specification discloses the effects of a compound with respect to a mouse skin graft rejection model wherein the donor mouse was grafted onto a recipient mouse and N,N-dimethyl-N-[4-[[[2-(4-methylphenyl)-6,7-dihydro-5H-benzocyclohepten-8-yl]carbonyl]amino]benzyl]tetrahydro-2H-pyran-4-ammonium chloride was administered subdermally thereto.

This disclosure is clearly not predictable for any treatment modality for graft-versus-host disease and/or rejection reactions during heart, kidney, liver or bone marrow transplantation in a mammal. There are no working examples to support any such methodologies involving internal organs. The administered compound in the Example is structurally distinct from the elected specie, 1-acetyl -N-(3-{4-[4-(aminocarbonyl)benzyl)-1-piperidinyl}propyl)-N-(3-chloro-4-methylphenyl)-4-piperidinecarboxamide. As previously evidenced by The Merck Manual, the treatment for transplantation is still somewhat limited and unpredictable.

The rejection of record of claims 1, 3 and 12 under 35 U.S.C. 112, first paragraph, is maintained because one skilled in the immunology art would have had to engage in extensive testing to determine which particular type of rejection reaction responds to a particular compound. Considering the state of the art, unpredictability of treatment and the total lack of support drawn to the treatment of graft-versus-host

disease and/or rejection reactions during heart, kidney, liver or bone marrow transplantation, i.e., support that is commensurate in scope with the claims, one of ordinary skill in the immunology arts would be burdened with undue experimentation to treat heart, liver, kidney or bone marrow rejection reactions comprising administering the instantly claimed "CCR antagonists."

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1, 3 and 12 are rejected under 35 U.S.C. 102(e) as being anticipated by Miki et al., U.S. Patent 7,049,441.

Miki teaches a Compound X, 1-acetyl -N-(3-{4-[4-(aminocarbonyl)benzyl)-1-piperidinyl}propyl)-N-(3-chloro-4-methylphenyl)-4-piperidinecarboxamide, for use in the treatment of graft versus host disease, a complication of bone marrow transplantation. See column 30, lines 45-54, as well as Examples 9-11, columns 42-44.

No claim is allowed.

Applicants' Amendment necessitated the new ground of rejection presented in this Office Action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this Final Action is set to expire THREE MONTHS from the mailing date of this Action. In the event a first reply is filed within TWO MONTHS of the mailing date of this Final Action and the Advisory Action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the Advisory Action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the Advisory Action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this Final Action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Phyllis G. Spivack whose telephone number is 571-272-0585. The examiner can normally be reached on 10:30 AM-7 PM.

If attempts to reach the Examiner by telephone are unsuccessful after one business day, the Examiner's supervisor, Ardin Marschel, can be reached on 591-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

October 2, 2009 /Phyllis G. Spivack/

Primary Examiner, Art Unit 1614